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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,628	07/24/2003	Gerrit Koppert	KOPPERT1A	9050
1444	7590	04/18/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 04/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/625,628

Applicant(s)

KOPPERT, GERRIT

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12,16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **STATUS OF THE APPLICATION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2006 has been entered.

2. The terminal disclaimer filed on February 23, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,686,517 has been reviewed and is accepted. The terminal disclaimer has been recorded.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action, mailed August 11, 2005.

Those rejections or objections not specifically addressed in this Office Action are withdrawn in view of Applicant's amendments.

Claims 3 and 13-15 have been cancelled and claim 8 has been amended. Claims 1, 2, 4-12, 16 and 17 are under examination.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

4. Claims 1, 2, 4-12, 16 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed December 29, 2005, as applied to claims 1, 2 and 4-17.

Applicant argues that the claims are not drawn to a broad genus, but to one specific species, namely *Raphanus sativa* and that limiting the claims to one specific *R. sativa* line, namely V33, would be overly limiting (see page 7, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs of 'Remarks' filed February 23, 2006).

This is not persuasive. The Examiner is not referring to the genus *Raphanus* in the scientific sense when stating that the specification fails to provide a written description of the broad genus of *R. sativa* plants. The Examiner is aware that the claimed invention is drawn to the species *R. sativa*. The written description rejection is applied because Applicant is claiming any and every *R. sativa* plant, obtainable by screening *R. sativa* plants for their ability to produce sprouts with at least some purple coloring, characterized in that the selected sprout comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of said anthocyanins have a anthocyanidin moiety of a described structure.

Applicant was not in possession of any and every *R. sativa* plant with the above described characteristics and the specification fails to provide a written description of said plants in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of any and every *R.*

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*sativa* plant with the above described characteristics. The specification only provides support for written description of *R. sativa* line V33 and not any and every *R. sativa* plant, obtainable by screening *R. sativa* plants for their ability to produce sprouts with at least some purple coloring, characterized in that the selected sprout comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of said anthocyanins have a anthocyanidin moiety of a described structure.

Again, the Examiner refers Applicant to *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

As the invention is broadly claimed, the claimed invention would not be distinguished from any other *R. sativa* plant with the same characteristics, unless the claims are amended to read on *R. sativa* line V33. In fact in Applicant's 'Remarks', filed February 23, 2006, on page 9, 1<sup>st</sup> paragraph state "[t]he *Raphanus sativa* V33 that was deposited has the herein claimed anthocyanin levels". Applicant is correct in stating that "one skilled in the art can readily breed plants having anthocyanin levels that are at least a certain percentage of the anthocyanin levels [using *Raphanus sativa* V33]" (see page 9, 1<sup>st</sup> paragraph of 'Remarks' filed February 23, 2006); however, this does not provide an adequate written description for any and every *R. sativa* plant, obtainable by

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screening *R. sativa* plants for their ability to produce sprouts with at least some purple coloring, characterized in that the selected sprout comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of said anthocyanins have a anthocyanidin moiety of a described structure. It only provides a written description for *R. sativa* line V33.

The ability of the public successfully to design around -- to use the patent disclosure to design a product or process that does not infringe, but like the claimed invention, is an improvement over the prior art -- is one of the important public benefits that justify awarding the patent owner exclusive rights to his invention (*ATD Corp. v. Lydall Inc.* (DC EMich) 43 USPQ2d 1170, 1178). On the one hand, claims must be "particular" and "distinct," as required by 35 U.S.C. § 112, so that the public has fair notice of what the patentee and the Patent and Trademark Office have agreed constitute the metes and bounds of the claimed invention. Notice permits other parties to avoid actions, which infringe the patent, and to design around the patent (*London v. Carson Pirie Scott & Co.* (CA FC) 20 USPQ2d 1456, 1458).

Applicant further cites *Enzo Biochem, Inc. v. Gen-Probe, Inc.* where it is stated

"reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement." (see page 9, end of 1<sup>st</sup> paragraph of 'Remarks' filed February 23, 2006).

The Examiner agrees with Applicant's argument with regards to *Enzo Biochem, Inc.* In fact, the argument further supports the Examiner's argument for lack of written description. The deposited line, V33, does constitute an adequate description; however,

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such a deposit does not constitute an adequate written description for any and every *R. sativa* plant, obtainable by screening *R. sativa* plants for their ability to produce sprouts with at least some purple coloring, characterized in that the selected sprout comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of said anthocyanins have a anthocyanidin moiety of a described structure, as is broadly claimed.

Applicant argues that there is no undue experimentation for one skilled in the art to determine if another line of *R. sativa* has the required anthocyanin levels (see page 9, 2<sup>nd</sup> paragraph of 'Remarks' filed February 23, 2006). The Examiner will address this in the 112, first paragraph rejection with regards to lack of enablement.

Applicant argues that breeding methods for obtaining *Raphanus sativa* plants that contain more than 800 nmol/g of fresh sprout material have been described (see page 10, 2<sup>nd</sup> paragraph of 'Remarks' filed February 23, 2006).

This is not persuasive. See MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.

In summary, the specification fails to provide an adequate written description for any and every *R. sativa* plant, obtainable by screening *R. sativa* plants for their ability to produce sprouts with at least some purple coloring, characterized in that the selected sprout comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of

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sprout, whereby the majority of said anthocyanins have a anthocyanidin moiety of a described structure as is broadly claimed.

***Claim Rejections - 35 USC § 112, first paragraph - Enablement***

5. Claims 1, 2, 4-12, 16 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed December 29, 2005, as applied to claims 1, 2 and 4-17.

Applicant argues that one skilled in the art is fully capable of making all of the plants having anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of anthocyanins have a moiety of the structure of formula 1. Applicant further argues that Example 4, on page 12 of the specification provides detailed instructions as how to extract anthocyanins from a plant to determine the anthocyanin context of any given plant (see page 11, 2<sup>nd</sup> paragraph of 'Remarks' filed February 23, 2006).

This is not persuasive. Applicant's assertion that Example 4, on page 12 of the specification provides detailed instructions as how to extract anthocyanins from a plant to determine the anthocyanin context of any given plant has nothing to do with enabling one skilled in the art to make and use the claimed invention. The Examiner disagrees



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that one skilled in the art is fully capable of making all of the plants having anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of anthocyanins have a moiety of the structure of formula 1. As stated in the Office Action mailed December 29, 2005, the rejection is not based on the ability to make a *Raphanus sativa* plant, but rather the fact that the claims do not state that the claimed *Raphanus sativa* plant has been deposited (see page 5, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs). Without a proper deposit, it would require undue trial and error experimentation for one skilled in the art to make and use the invention as claimed because one skilled in the art would have to screen literally thousands of *Raphanus sativa* plants to determine which, if any, of said plants would have anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of anthocyanins have a moiety of the structure of formula 1.

Applicant argues that the present specification provides various means to enable the skilled person to make the claimed invention and gives examples using lines V33, CGN 6924 and CGN 7240 (see page 11, last paragraph).

The Examiner agrees that using lines V33, CGN 6924 and CGN 7240 would enable the claimed invention; however, these lines are not used in the claims and thus the claims are broadly drawn to any and every *R. sativa* plant, obtainable by screening *R. sativa* plants for their ability to produce sprouts with at least some purple coloring, characterized in that the selected sprout comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of said anthocyanins have a anthocyanidin moiety of formula 1. Therefore, undue trial and error

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experimentation would be required for one skilled in the art to make and use the claimed invention.

In response to Applicant's argument based upon the age of the references (see page 12, 1<sup>st</sup> full paragraph of 'Remarks' filed February 23, 2006), contentions that the reference is old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Applicant argues that it is not necessary to understand the genetic basis of anthocyanin accumulation in order to enable one skilled in the art to make plants of the invention.

This is not persuasive. The Examiner has provided evidence that shows that the genetic interactions that confer a trait of anthocyanin accumulation are polygenic and unpredictably genetically complex in *Raphanus* (see page 6, 2<sup>nd</sup> paragraph of the Office Action mailed December 29, 2005) and Applicant has failed to provide any evidence to overcome the cited reference. The reference was used to show the unpredictability of breeding for anthocyanin accumulation. Applicant states "V33 is a line that does not divide out green descendants, i.e. all progeny sprouts are dark purple" (see page 14, 2<sup>nd</sup> paragraph of 'Remarks' filed February 23, 2006). This may very well be true for line V33, but the specification has not shown that all *Raphanus sativa* plants have this characteristic; therefore, it would require undue trial and error experimentation for one skilled in the art to screen literally thousands of *Raphanus sativa* plants to determine which, if any, of said plants would have anthocyanins at a level of at least 800 nmol per

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gram fresh weight of sprout, whereby the majority of anthocyanins have a moiety of the structure of formula 1.

Applicant argues that Savoskin et al support patentability of the claimed invention because Savoskin et al is contrary to what would have been expected (see page 14, 3<sup>rd</sup> paragraph).

This is not persuasive. The Savoskin et al reference was cited to show the unpredictability in genetic interactions that confer a trait of anthocyanin accumulation and Applicant has not provided evidence to overcome the reference.

### ***Claim Rejections - 35 USC § 102***

6. Claim 16 remains rejected under 35 U.S.C. 102(b) as being anticipated by Giusti et al (J. Agric. Food Chem. 46: 4858-4863, 1998), as stated on page 11 of the Office Action mailed August 11, 2005.

Applicant argues that Giusti et al do not anticipate the claimed method because the claim is drawn to a method of using *Raphanus sativa* plants comprising at least 800 nmol/g fresh weight sprout.

This is not persuasive. The Examiner does not concede, as Applicant states on page 15, 3<sup>rd</sup> paragraph of the 'Remarks' filed February 23, 2006, "that such plants are not disclosed in Giusti et al". Upon further review of both the Office Actions mailed August 11, 2005 and December 29, 2005, the Examiner could not find any such concession.

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The Examiner maintains that Giusti et al do anticipate the claimed method as stated on page 11 of the previous Office Action mailed August 11, 2005. Applicant's argument that the method uses *Raphanus sativa* plants comprising at least 800 nmol/g fresh weight sprout does not overcome the rejection because Applicant has not provided evidence that the method used by Giusti et al does not use *Raphanus sativa* plants comprising at least 800 nmol/g fresh weight sprout.

### **Conclusion**

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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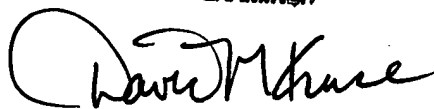
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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

April 10, 2006

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse". The signature is written in a cursive style with a large initial "D".